The Negotiated Rulemaking Committee on Special Payment Provisions for Prosthetics and Certain Custom-Fabricated Orthotics Meeting

February 10-11, 2003 – Meeting #4

Day 1 – February 10, 2003

The Negotiated Rulemaking Committee on Special Payment Provisions for Prosthetics and Certain Custom-Fabricated Orthotics convened on February 10, 2003, at the Pikesville Hilton in Pikesville, Maryland for its fourth meeting. Shortly before 9:30 a.m., Commissioners Lynn Sylvester and Ira Lobel with the Federal Mediation and Conciliation Services (FMCS) called the meeting to order. Ms. Sylvester welcomed the committee's newest member, the primary for the American Academy of Physical Medicine and Rehabilitation, Dr. Charles E. Levy, to the group (Attachment 4.1 - Sign-in Sheet). After distributing the agenda (Attachment 4.2 – Rolling Agenda), Mr. Lobel led the committee through a review of the minutes from the January 6-7, 2003, meeting. Noting minor corrections, the committee approved the minutes by consensus (Attachment 4.3 – January 6-7, 2003 Minutes).

The committee immediately embarked on the task of discussing the "decision tree" criteria drafted to determine which custom-fabricated orthoses should be included on the list of approved items for purposes of the special payment provisions required by Section 427 of the Benefits Improvement and Protection Act (BIPA) of 2000 (Attachment 4.4 – Decision Tree). At the suggestion of one of the members, the format (not the content) of the document was changed to read more like statutory language (Attachment 4.5 – Inclusion Criteria for Custom-Fabricated Molded to Patient Model Orthotic Devices). Referring to this document, a committee member suggested adding a footnote to the second criteria item—the orthotic device must be identified by a base procedure code—that deals with exceptions, e.g., code 99. With this addition, the committee approved the document by consensus.

As a result of the CMS presentation on "L" Code Structure and Terminology by Joel Kaiser being moved to the second day of the meeting, the next item for discussion was the report on NOMA's position by Stuart Kurlander (Attachment 4.6 - Memorandum). Mr. Kurlander provided a brief overview of the NOMA proposal and noted one typographical in the document (on page 3, item B.1.c, the word *over* was changed to *utilizing*). In reference to Section C of the document, Inclusion/Exclusion Based on Definitions and Fabrication Techniques, a committee member asked if the group should only make recommendations on existing technology. NOMA's position was "it didn't seem relevant to make decisions on things that don't exist today. Furthermore, in terms of priority, the committee should consider existing technology, and then move to address future possibilities." With the issue of technology raised, a member of the committee suggested postponing the remainder of the NOMA presentation until the group heard the

CAD CAM (Computer Aided Design and Computer Aided Manufacturing) presentation that was scheduled to follow. The rationale for this decision was the fact that the CAD CAM presentation was expected to address many cutting edge technology processes. The group agreed to halt the NOMA presentation to hear the CAD CAM information.

Michael Brncick gave the CAD CAM presentation, entitled: "Computer Aided Design and Computer Aided Manufacturing in the Prosthetics and Orthotics Profession." He began the presentation by providing a discussing a number of terms/definitions:

- Impression (negative impression)
- Positive Model (mold, model, cast)
- Apply Template
  - -modify cast
  - -rectify the model (or mold)
- Fabrication
  - -orthosis
  - -prosthesis
- Fitting
  - -anatomical alignment
  - -biomechanical objectives

Next, Mr. Brncick reviewed techniques used to produce orthoses and prostheses, including molded to patient model (MTPM), molded to patient (MTO), and made to measure (MTM).

To facilitate the group's understanding, Mr. Brncick provided numerous tangible displays and showed flow charts illustrating the techniques discussed, noting that the molded to patient model (MTPM) is currently the standard in the field.

Impression

↓ ***Molded to Patient Model Process***

Positive Mold

↓

Apply Templates (Rectify/Modify) → Fabricate → Fitting

As part of his presentation, Mr. Brncick showed a video from the Newington Distance Learning Program. The video highlighted CAD CAM, showing how body segments are digitized and data from the computer goes to the carving machine. Mr. Brncick noted that the knowledge and skill base of professionals is not diminished when one moves from a manual to a CAD system. Following his presentation, Mr. Brncick responded to questions from the committee.

Q: How do the technicians who assist the prosthetist/orthotist know what to do?

A: The technicians have schooling and they take direction from the prosthetist/orthotist.

Q: How many practices use the CAD technique?
A: About 10% to 12% use it on a regular basis.

Q: What is in use more for protheses, plaster or CAD?
A: I would have to get that information. (Response from Hanger representative – 30% use CAD).

Q: What is in use more for orthoses, plaster or CAD?
A: Response from Hanger representative – 30% to 50% of spinal orthoses use CAD.

Q: Are there standards in the industry regarding how you measure, fit, make a device. For example, should it last 5 years?
A: There are no such benchmarks, but there are follow-up criteria that are used for checks and balances. We are developing standards of practice but you must note, if a patient has a change (e.g., volume weight change) the device will have to change. We do have functional levels to assess the effectiveness of a device. These levels, called K-levels, are standardized in the industry (for protheses).

The group next moved to review the Orthotic Base Codes 2003 matrix (Attachment 4.7). Committee member Terry Supan provided an expanded version of base code document, detailing for each HCPCS Code, if the item was also included on the list in the NOMA proposal (Attachment 4.8). He noted that an "A" on his matrix indicated that the item was on NOMA's first list and a "B" on his list meant the item was on NOMA's second list. Theresa Linkowich, Health Specialist, CMS, also informed the group that CMS provided the committee with a list of L codes pertaining to custom-fabricated orthotics and prosthetics in their CMS-issued binder. With three documents to consider, the facilitators instructed the committee to work individually or in groups to compare the lists and see what they would add or delete from the CMS list. By undertaking this exercise, they explained, the committee might be better positioned to develop a definition for "positive model."

When the group reconvened, a number of suggestions regarding the codes where shared, including:

- Because MTPM was part of the L code system in 2000, the terminology was relevant. However, CMS has since made changes and now they need to justify/explain the changes before the committee can proceed effectively.

- CMS should utilize a modifier system to handle situations where one person uses a procedure with a "model" and another person can obtain the same end result without a "model." Essentially, there would be 3 categories (all based on medical necessity and practicality): 1) always in, 2) never in, 3) sometimes in. It was noted that physical therapists and physicians are accustomed to using modifier systems where

they bill according to a code and then modify the submission by adding notes to justify exceptions.

- Use the MTPM as defined in the Region B DMERC supplier manual under the TLSO section (Attachment 4.9 – Chapter 17 Medical Policy, Region B DMERC Supplier Manual).

- Use definition from SADMERC or Region A DMERC (Attachment 4.10 – SADMERC and Region A DMERC Definitions).

- Add the provision of a measurement process to create a positive model over the patient definition to the SADMERC language.

The group agreed to consider all the options proposed overnight and to continue its discussion the following day.

One member of the public audience, John Wall, addressed the committee when the floor was opened for public comment. Mr. Wall contrasted for the committee what he felt he could do when he practiced as a registered physical therapist versus his practice as a certified orthotist/prosthetist. Two main points of his address were 1) PTs are not qualified to do P/O work, and 2) PTs and OTs need to have access to only the L codes for which they are educated, bill for, and provide services for. To support his argument, he had numerous of his colleagues submit letters expressing similar sentiments to the committee (See Attachment 4.11). In response to his comments, several committee members questioned his organizational affiliations, the accreditation of his academic institution and its curriculum, and the appropriateness of his statements.

Day 2 – February 11, 2003

The second day of the Negotiated Rulemaking Committee on Special Payment Provisions for Prosthetics and Certain Custom-Fabricated Orthotics meeting began shortly after 8:00 a.m. The first topic of discussion, seemingly as a result of the public comment made the day prior, was how the committee should respond to controversial remarks made by members of the public. Among the suggestions included:

- Allowing members of the public when addressing the committee to decline questions if they choose,
- Having committee members respond to public comments the following day (if possible),
- Having the committee respond to public comments immediately after hearing from each addresser,
- Allowing response from the committee only after all addressers have spoken,
- Requesting that the facilitators identify where each speaker is from and whom they represent.

After considering all the suggestions, the committee agreed that the facilitators, where possible, would get organizational and affiliation information from each member of the public audience that addressed the committee, each public speaker would continue to be limited to a 5 minute time limit and could accept questions for 1-2 minutes following his/her presentation (if they wished), and at the conclusion of all the public comments, the committee would be permitted to respond to any of the comments made.

The committee next moved to discuss a definition for Molded to Patient Model (MTPM). The following preliminary definition was drafted:

Molded to Patient Model is a particular type of custom fabricated orthosis that describes the way the orthosis is formed. The orthosis is individually fabricated over a rectifiable positive model to the patient, based on a three-dimensional representation or replication of the specific body part. The negative impression is made from measurements or using plaster or fiberglass casting material or use of other impression making means, or CAD CAM digital scanning model. The orthosis is then custom fabricated and molded on this positive model.

After reviewing the definition, the committee posed many questions, most directed to NOMA representative Stuart Kurlander.

Q: Why is NOMA against MTM? Is it in the best interest of the patient?
A: We are for MTM. It is in the best interest of the patient. We fully support it. We just don't think it's a form of MTPM as defined in the legislation and therefore we don't consider it covered under this statute.

Q: Why does NOMA want MTM excluded?
A: We don't think the skill sets represented around the table are necessary to make a measurement product. If we include MTM as a type of custom fabrication, then we would be including every type of custom fabrication in the rule.

Q: Other than the MTM issue, what issues/concerns are there with using the Region B DMERC definition?
A: The principle bone of contention with the Region B DMERC definition is section B. (Section B reads: Detailed measurements are taken of the patient's torso and are used to modify a positive model (which has been selected from a large library of models) to make it conform to the patients body shape and dimensions.)

Q: Excluding section B, can the committee agree with the rest of the Region B definition?
A: Yes, as long we remove the language that refers to thoracic-lumbar-sacral orthoses (TLSO).

After a short break, the committee asked questions of CMS representatives Joel Kaiser, Health Insurance Specialist Centers or Medicare Management and Dr. and Laurie

Feinberg, Medical Officer, Centers for Medicare Management regarding CMS's L code structure and terminology.

Q: Why did MTPM get dropped in some of the L code descriptors?
A: There were revisions for TLSO, otherwise, nothing has changed. It might have been an oversight.

Q: There were 35 MTPM descriptors in 2000, now there are 9. Is this right?
A: There are 16 now according to my count. Our workgroup can take another look at this.

Q: Are you moving to two categories, one being custom fabricated and the other pre-fabricated?
A: That might be true but I don't recall discussing this in the workgroup. Either it's MTPM or it isn't.

Q: What is your definition of custom fabricated?
A: It's a general term. It doesn't mean a specific type. It includes different techniques.

Q: Could there be a modifier used as an indicator?
A: It is always better to develop policy and then look at the coding for implementation of the policy.

Q: The committee is currently considering three categories of devices: MTPM (which we will likely reach consensus), items not covered under the law, and a middle group comprising items that may be covered in one instance as MTPM and in another circumstance in may not be MTPM. Will this be ok?
A: We look at each device like that, to make a list of orthotics and prosthetics and t hen decide the appropriate way to implement the policy.

Q: What process did you use to come up with the CMS list?
A: We just used codes with the MTPM descriptor. If there is a code without the descriptor we will consider it.

Q: Do you have a working definition of MTPM?
A: Not as far as HCPCS go, but our contractors that process claims have definitions.

Q: Are items on the CMS list based on clinical complexities?
A: The goal is to serve the beneficiary's needs, but we must adhere to the law.

Q: Without a working definition of MTPM and custom fabrication, how is a decision made regarding codes?
A: We look at available products, ones provided to patients, and try to make codes according to what people order.

Q: What is the difference between the definitions used by the contractors?
A: I don't know the differences. If there is no national guidance the contractors can use their discretion with definitions as long as they don't deviate from what the law intends. Custom fabricated and MTPM seem synonymous. We didn't focus on this issue as closely as we perhaps need to. We'll (the workgroup) have to look at it again.

Q: Can you explain the CPT billing process and L code billing?
A: It's complicated. According to HCPCS standards, CPT codes refer to service, generally. We thought double payment was unlikely. There was no intention for there to be overlap. If it becomes a problem, we'll have to change it. When you bill an L code, you are expected to provide/deliver a well fitting device. We take into account the materials used and your expertise in fabricating it.

Q: So, what does the L code include?
A: For "custom" devices it includes the whole process—from the patient coming in for evaluation to leaving with a well fitting device.

Q: What is the criteria for who can bill L codes?
A: There is a provider enrollment process.

Q: Why did you include language referring to adjustment levels?
A: We did this in response to people asking questions. It's just for clarification.

Q: What is included with L 1940?
A: You should get a fully functioning orthosis.

Q: If I go to a P/O, do I get the same reimbursement?
A: There's always a range of products in each code but yes, it should be the same.

Q: What happens to items not on the list (regarding payment)?
A: We establish standards on who can provide the items. So whoever provides that is not "qualified" will not be paid. We will have codes that identify items covered. It's either yes it's covered or no it isn't covered.

Q: If something is not on the list, does it get paid as usual?
A: This list only establishes who is eligible to provide the service. I urge you to look at the codes to identify what qualifications are needed for each code. Items not paid on the list are covered and paid as usual.

Q: Will we get a report if you make code changes?
A: Yes, either written or verbally.

Q: If it is MTPM, should we submit it under code "99"
A: No, I don't believe so. If you did, it would probably get re-coded when we receive it.

Q: Are there any custom fabricated orthoses that don't require experience/education to custom fabricate?
A: Off the top of my head I don't think so. The whole idea is you have an understanding of physiology to do the custom fabrication.

Q: What happens to a code that goes away?
A: Either people were no longer billing the code, or its billed under an existing code, or a new code is created. If it's low volume use of the code, it goes to a miscellaneous code.

Q: Do you track the frequency of use of codes before eliminating them?
A: Yes. It's uncommon to close a code because of low use. Usually we see new products come along and to accommodate them we may reconfigure existing codes.

Q: Do you track supplier type with code usage?
A: We don't do it but it's potentially possible to run such a report.

Before leaving, Dr. Feinberg encouraged the committee to submit in writing things they consider custom fabricated to her at: lfeinberg@cms.gov.

After a short break, the committee briefly discussed the issue of including all prosthetics on the list. There was a general sense of agreement, but a few members noted that there would be specific codes that should not be included, e.g., breast and penile protheses. The reason for this, they cited, was the intent of the legislation is to focus on limb protheses. CMS agreed to come up a definition for "item of prosthetic." In addition, John Michael agreed to compile the list of L codes (and/or V codes) for prosthetics.

The committee next considered how to define "custom fabricated." After significant discussion, the group was asked to consider to the following global definition during the lunch hour:

Orthotic devices individually fabricated for a specific patient, which involve a specific body segment, that have been molded or fabricated for the patient utilizing a positive model, a template model, anatomical measurements, negative impression, direct forming or computer aided design and computer aided manufacturing (CAD/CAM) for the development of a individually designed orthotic device.

Custom fabricated items not molded to the patient model are not included on the list of items provided by the Secretary under this section 427 unless individually adjusted by the provider in material ways (for example, ways more significant than addition of a piece of foam or tightening of a strap.) Items molded to the patient will not be included on the list.

After lunch the committee was polled for their reaction to the definition (above). The committee agreed with the first paragraph, but could not reach consensus on the second paragraph. The group once again engaged in debate before arriving at its final pass on definitions to designate items that would be included in the statute versus those outside the statute.

Custom Fabricated Orthoses (Outside the Statute)
Orthoses that are individually custom fabricated for a specific patient using a specific template that has been selected based on anatomical measurements.

Orthoses that are individually fabricated by direct forming the orthosis over a specific body segment or structure of the patient.

(It is noted that the group wanted to consider use of the word "fabrication" further.)

Certain Custom Fabricated Orthoses (Within Statute)
Orthoses which are individually fabricated for a specific patient and molded or fabricated over a specific positive model of the patient, which has been developed from an impression, anatomical measurements, and/or the use of computer aided design (CAD) impression technology of a specific body segment or structure of the patient for the purpose of developing a custom fabricated orthosis.

In an attempt to reach consensus on the definitions above, it was suggested that various groups represented on the committee (BOC, ABC, NOMA, OTs, PTs) provide presentations at the next meeting regarding what staff (i.e., aides, technicians) are authorized to do. In response to the request, a PT representative stated that aides (for PT, OT and Hand Therapists) merely clean and help maintain the facility. They are not allowed to do "work" because Medicare will only provide reimbursements for work done directly by the therapist. This statement resulted in a number of additional questions, as follows.

Q: Can PT assistants do wound care?
A: There is a 2-year degree to be a PT assistant and they can't do any service involving evaluation of the patient.

Q: Could a PT assistant be involved in making an orthosis?
A: Any skilled service that involves any degree of evaluation has to be done by the PT.

Q: If the orthosis is in the prescribed care plan, could a PT assistant be involved?
A: The PT does all the evaluation components. Any follow-on assessment is also done by the PT.

Q: Can fabrication of an orthosis also be done by an outside fabricator/contractor (e.g., AFO)?

A: Some do work in that manner. (Additional response – More commonly than not, PTs and OTs make devices themselves.)

Before the meeting closed, AOPA made a formal request for NOMA to disclose the names of its members. In response to this request, facilitator Ira Lobel stated, stated that I am going to respond to this request. As convenors, Lynn and Ira made recommendations to CMS based on extensive interviews with many people in the field. One of the requirements of the statute was to include a representative of manufactures. We suggested NOMA. At this juncture in the process, it does not matter who the membership of each organization is, since all of you have been duly selected to serve on the committee and the committee is ruled by consensus on all matters including membership on the committee. Whether NOMA or any other members chooses to divulge their membership is up to them; they must all live with the consequences of their decisions. Having said this lets move on to other topics. If NOMA chooses, they can disclose that information to AOPA in private." With this, a call was made for Public Comments. There was none.

Items for the next meeting's agenda were posted (see below) and the meeting was adjourned shortly before 4:00 p.m.

Agenda for March 10-11 Meeting

- Reach consensus on prosthetics
- Finish discussion on definitions of custom fabrication
- Hear presentations from ABC, BOC, and NOMA (2-3 minutes) regarding the role of various individuals involved in custom fabrication delivery of care (what does assistant, technician, etc.)
- Define qualified provider and supplier
- Review CMS list of L code modifications and prosthetic list
- Reporting back from Joel Kaiser and/or Laurie Feinberg (if they are available)
- Finally, Kim Doolan will send emails to various groups asking what services a beneficiary could receive from them.

Attachment List

Attachment 4.1 - Sign-in Sheet
Attachment 4.2 – Rolling Agenda
Attachment 4.3 – January 6-7, 2003 Minutes
Attachment 4.4 – Decision Tree
Attachment 4.5 – Inclusion Criteria for Custom-Fabricated Molded to Patient Model Orthotic Devices
Attachment 4.6 – Memorandum
Attachment 4.7 – Orthotic Base Codes 2003
Attachment 4.8 – Orthotic Base Codes 2003 (From Mr. Supan)
Attachment 4.9 – Chapter 17 Medical Policy, Region B DMERC Supplier Manual
Attachment 4.10 – SADMERC and Region A DMERC Definitions

Attachment 4.11 – American National Standards Institute (ANSI), Standard Activities Overview*
Attachment 4.12 – International Organization for Standardization (ISO), Overview*
Attachment 4.13 – Coalition for Professional Certification, Requirements for Bodies Operating Certification Systems for Persons*
Attachment 4.14 – Public Comment Letters

* Additional documents provided to the committee for general reading.